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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,890	12/21/2001	William M. Canfield	203510US77	5459

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,890	CANFIELD, WILLIAM M.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-21,23-58 and 60-65* is/are pending in the application.

4a) Of the above claim(s) *18,36-55 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-17,19-21,23-35,56-58 and 60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/03, 9/03, 12/03,* 4/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 4, 22 and 59 have been canceled. Claims 1-3, 5-21, 23-58, and 60-65 are still at issue and are present for examination.

Claims 18, 36-55 and 65 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 6/23/03.

Applicants' arguments filed on 3/24/04, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-17, 19-21, 23-35, 56-58, and 60-64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/023,889. The rejection is explained in the previous Office Action.

Applicant's request that this rejection be held in abeyance is noted but the rejection will be maintained until a terminal disclaimer is filed or other appropriate action taken.

Claims 11, 12, 16, 29, 30, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is explained in the previous Office Action.

Applicants argue that the specification on page 20 defines the term "stringent conditions" as conditions under which polynucleotides having at least 70% identity will hybridize. However, the portion of the specification referred to by applicants says

> "Polynucleotides which encode the α and β subunits of GlcNAc-phosphotransferase or soluble GlcNAc-phosphotransferase mean the sequences exemplified in this

> application as well as those which have substantial identity to those sequences and which encode an enzyme having the activity of the α and β subunits of GlcNAc-phosphotransferase. Preferably, such polynucleotides are those which hybridize under stringent conditions and are at least 70%, preferably at least 80% and more preferably at least 90% to 95% identical to those sequences."

This portion of the specification does not clearly **define** stringent conditions as those at which polynucleotides having 70% identity will hybridize as it recites the ability to hybridize under stringent conditions and the % identity as distinct features of polynucleotides intended to be encompassed. As any "definition" of the term stringent conditions found in this passage is vague and unclear at best, applicants cannot upon this to define a term used in the claims. If applicants intend to encompass polynucleotides having 70% identity it is suggested the claims be amended to specifically recite this value.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 6, 19-21, 23, 24, 56-58, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Hove et al. in view of Mulligan et al. (US Patent 6,224,858) and Gottlieb et al. The rejection is explained in the previous Office Action.

Applicant argue that lectin resistant cell lines were known and therefore to produce a lysosomal hydrolase with reduced complex carbohydrates, one could use a known lectin resistant cell line and introduce a expression vector carrying the polynucleotide that would encode the lysosomal hydrolase and that this is what is commonly done in the field. Applicants state that the present claims however, provide for introducing the polynucleotide encoding the lysosomal hydrolase and then culturing the transfected cell with a lectin to obtain a lectin resistant cell which expresses the lysosomal hydrolase. Therefore, the order in which the steps of the claimed method are performed is different. This is not persuasive because while the order of the steps performed may differ from many methods described in the art they do **not** differ from the order taught by the Mulligan et al. reference cited in the instant rejection. The Mulligan et al. reference evidences that the art was clearly aware that the order these steps are preformed could

be reversed. The rejection as presented did not suggest that the methods of the references cited by applicants be used but the methods described by Mulligan et al be applied to the production of a lysosomal hydrolase. Merely because other art might suggest alternative means of achieving the desired goal does not negate the suggestion of Mulligan et al. that the same goal can be achieved by the claimed method.

Claims 7, 11-14, 16, 17, 25, 29, 30-32, 34, 35, and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Hove et al. in view of Mulligan et al. (US Patent 6,224,858) and Gottlieb et al. as applied to claims 1-3, 5, 6, 19-21, 23, 24, 56-58, and 61 above, and further in view of Bao et al. and Kornfeld et al. The rejection is explained in the previous Office Action.

Applicant has not presented any arguments specifically traversing this rejection but instead relies upon the traversal discussed above. Therefore, this rejection is maintained for the reasons presented above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Rebecca Prouty
Primary Examiner
Art Unit 1652